Roche

Pharmaceuticals

00D-1543
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

U.S.A

Basel, December 19, 2001
Comments regarding Your Draft Guidance: "Electronic Records; Electronic Signatures, Glossary of Terms" (Docket No. 00D-1543)

Dear Madam, Dear Sir,

Thanks for the opportunity to comment on this guidance.

Your guidance was internally forwarded to a Roche expert group for electronic records and signatures. for comments. This expert group has roughly 50 members from various countries. Please find enclosed consolidated comments from this group.

1. General
Comment. This Guidance seems very incomplete. The Glossary contains only 14 terms.

2. Chapter 2.1 Applicability
Current draft: This draft guidance applies to electronic records and electronic **signatures** that persons create, **modify**, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal...

Suggested text: This draft guidance applies to electronic records that persons create, modify, maintain, archive, retrieve, or transmit and electronic signatures under any records or signature requirement set forth in the Federal...

Reason: Signatures need to be treated separately. The current text could imply that signatures could be modified.

3. Definition: Computer Systems Validation
Current Draft: Confirmation by examination and provision of objective evidence that computer system specifications conform to user needs and intended uses, and that all requirements can be consistently fulfilled.

Suggested Text: Validation is establishing documented evidence that provides a high degree of

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assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. [1987 "Guideline on General Principles of Process Validation," Comment 66, of 21CFR11]

Comment: The new definition is more a design qualification. It is only checked if system specs are conforming to user needs. User needs are defined in the user requirements. There is no rationale to replace a well established definition.

Yours sincerely,

F. Hoffmann-La Roche Ltd.

Peter Bosshard

Wolfgang Schumacher